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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,838	10/15/2001	Ornella Flore		1712

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Thomas A. O'Rourke
Wyatt, Gerber, Meller & O'Rourke
99 Park Avenue
New York, NY 10016

EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,838

Applicant(s)

FLORE, ORNELLA

Examiner

Michael C. Henry

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 5-8 and 9 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Kiyosuke et al., (JP 10330256).

In claim 7, applicant claims a pharmaceutical composition for treating Epstein Barr virus, comprising a therapeutically effective amount of a triterpenoid acid having a given structural formula. Kiyosuke et al., disclose applicant's claimed pharmaceutical composition (see abstract). The language pertaining to "treating Epstein Barr virus....." does not limit the instant claims. The instant claims only require the compound and a carrier. It should be noted that the

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examiner has interpreted the X in the structural formula as representing an OH as opposed to O, since the substitution of O for X would imply the absence of any possible stereochemistry.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al. (US 5,527,890).

In claim 8, applicant claims a pharmaceutical composition for treating Epstein Barr virus, comprising a therapeutically effective amount of a triterpenoid acid having a given structural formula. Rao et al. disclose applicant's claimed pharmaceutical composition. Rao et al. refers to this triterpenoid acid as a derivative of glycyrrhetic acid (col. 2, lines 11-69 and claim 4). The language pertaining to "treating Epstein Barr virus....." does not limit the instant claims. The instant claims only require the compound and a carrier.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takaishi et al (Phytochemistry, Vol. 45, No. 5, pp. 969-974, 1997) in view of Kiyosuke et al.,

In claim 5, applicant claims a method of treating Epstein Barr virus comprising the steps of administering to the patient a therapeutic, a derivative of a triterpenoid acid and wherein the triterpenoid acid has a given structural formula.

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Takaishi et al disclose a method of treating Epstein Barr virus using triterpenoids (see abstract).

The difference between applicant's claimed method and the method of Takaishi et al. is the specific triterpenoid used.

Kiyosuke et al. disclose applicant's triterpenoid acid (glycyrrhetic acid) used to treat human cancer cell lines (see abstract). Furthermore, it should be noted that Epstein-Barr virus has been associated with Burkitt's lymphoma, a cancer of the lymph nodes and the nasopharynx, the part of the pharynx (throat) which lies above the soft palate.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Takaishi et al., in view of Kiyosuke et al., and to use the triterpenoid acid like those disclosed by Kiyosuke et al., since a skilled artisan would reasonable expect to use any triterpenoid to treat Epstein Barr virus.

One having ordinary skill in the art would have been motivated, to use the process of Takaishi et al., in view of Kiyosuke et al., and to use the triterpenoid acid like those disclosed by Kiyosuke et al., since a skilled artisan would reasonable expect to use any triterpenoid to treat Epstein Barr virus.

It should be noted that in claim 10, applicant claims "the method of claim 1 wherein the dosage is in the range of 2.5 mg to 50 mg/kg." Therefore, claim 10 is also encompassed by the preceeding rejection, because the use of a specific dosage depends on factors like the severity of the disease and the age of the subject that is being treated.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takaishi et al (Phytochemistry, Vol. 45, No. 5, pp. 969-974, 1997) in view of Rao et al.

In claim 6, applicant claims a method of treating Epstein Barr virus comprising the steps of administering to the patient a therapeutic, a derivative of a triterpenoid acid and wherein the triterpenoid acid has a specific structural formula.

Takaishi et al disclose a method of treating Epstein Barr virus using triterpenoids (see abstract).

The difference between applicant's claimed method and the method of Takaishi et al. is the specific triterpenoid used.

Rao et al. disclose applicant's triterpenoid acid which is used for treatment or prevention of certain diseases including cancer (see abstract). Furthermore, it should be noted that Epstein-Barr virus has been associated with Burkitt's lymphoma, a cancer of the lymph nodes and the nasopharynx, the part of the pharynx (throat) which lies above the soft palate.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Takaishi et al., in view of Rao et al., and to use

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the triterpenoid acid like those disclosed by Rao et al., since a skilled artisan would reasonable expect to use any triterpenoid to treat Epstein Barr virus.

One having ordinary skill in the art would have been motivated, to use the process of Takaishi et al., in view of Rao et al., and to use the triterpenoid acid like those disclosed by Rao et al., since a skilled artisan would reasonable expect to use any triterpenoid to treat Epstein Barr virus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

September 16, 2002


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200